PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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- 5. Okt. 2004
HOFFMANN • EITLE, MÜNCHEN
PATENTANWÄLTE RECHTSANWÄLTE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing *(day/month/year)*	04.10.2004
Applicant's or agent's file reference 99 625 a/ubr	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/08067	23.07.2003	23.07.2002

Applicant
SHERWOOD SERVICES AG et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Schmidbauer, A Tel. +49 89 2399-8222

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
99 625 a/ubr		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/08067	23.07.2003	23.07.2002
International Patent Classification (IPC) or both national classification and IPC		
A61B17/42		
Applicant		
SHERWOOD SERVICES AG et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 12 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
29.01.2004	04.10.2004
Name and mailing address of the international preliminary examining authority:	Authorized Officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Daintith, N Telephone No. +49 89 2399-8894

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/08067

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

3, 5-15, 17	as originally filed
1, 2, 2a, 4, 16, 18, 19, 19a	received on 08.07.2004 with letter of 08.07.2004

Claims, Numbers

1-24	received on 08.07.2004 with letter of 08.07.2004

Drawings, Sheets

1/19-19/19	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-24
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-24
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-24
	No:	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The application concerns a surgical instrument for passing material into a body in a minimally invasive procedure.

2. WO02/39890 (D1) and US-A-5 112 344 (D2) disclose the closest prior art and both show an insertion instrument for inserting a support structure into the body to provide support for the urethra.

3. The invention lies in the specific shape of the hooked part of the instrument which curves first in one direction and then in the opposite direction. This optimises the surgical process of inserting material, e.g. a support tape, through the pelvis to support the urethra. None of the cited prior art shows nor suggests such a shape in the field of urethral supports and hence claim 1 is novel and inventive within the meaning of Article 33 (2) and (3) PCT.

4. The dependent claims 2 to 24 are hence also novel and inventive.

5. There is no doubt as to the industrial applicability of the instrument and hence the requirements of Article 33 (4) PCT are also met.

IVS OBTURATOR INSTRUMENT AND PROCEDURE

BACKGROUND

1. Technical Field

The technical field relates to insertion instrumentation for inserting material into the body and, more particularly, to an insertion tool and method for inserting a support structure or material into the body to provide a support to the urethra.

2. Background of Related Art

One problem occurring in women due to the onset of advanced age or trauma is urinary stress incontinence. Several therapies have been developed to correct or alleviate this condition, such as, for example drug therapies and surgical procedures. In some cases it is necessary to implant a temporary or permanent structure to support the midline of the urethra to control discharge.

Several surgical procedures have been developed to position a support against the urethra. Many of these procedures require the use and installation of bone anchors to affix the ends of the support to the pubic bone. These procedures are fairly invasive and require complex instruments to install the bone anchors in the pubic bone.

One exemplary device and method of inserting, in a minimally invasive manner, a sling support within the body to support the urethra is disclosed in certain embodiments of U.S. Patent No. 5,112,344 to Petros. The Petros

reference discloses the use of an instrument to insert a length of tape through incisions in the abdomen and the vagina so that the tape supports the urethra. No bone anchors or other auxiliary structures are used to anchor the tape. While inserting the tape into the body using the instrument, the instrument passes through the patient's body on either side of the bladder. Although this instrument is designed to safely pass from the incision in the vagina to the incision in the abdomen, surgeons typically perform a cystoscopy to check the integrity of the bladder.

It is desirable to have other methods of inserting, in a minimally invasive manner, support structure or material into the body without having to pass an instrument through the body on either side of the bladder.

SUMMARY

According to the present invention, there is provided a surgical instrument for passing a material into a body in a minimally invasive procedure comprising:

a first member having a longitudinal section defining a longitudinal axis and an arcuate section extending distally from the longitudinal section, wherein:

a proximal portion of the arcuate section curves away from the longitudinal axis in a first direction and defines a first radius of curvature; and

a portion of the arcuate section distal of the proximal portion curves toward the longitudinal axis in a second direction and defines a second radius of curvature. The shape of the first member facilitates the passing of the material into the body, in a minimally invasive

procedure.

The shape of the first member enables a material to be placed inside the body in a minimally invasive procedure so that the material extends through the obturator foramen.

In certain preferred embodiments, the first member comprises a hollow outer tubular member. A stylet is at least partially movable within the outer tubular member and engageable with a material to pass the material within the body. The hollow outer tubular member and stylet enable the surgeon to remove the stylet from the outer tubular member and reinsert the stylet in the opposite position with respect to the outer tubular member. This structure also facilitates the placement of the material so that the material extends from a first side of the pelvis to a second side of the pelvis.

A proximal portion of the arcuate section curves away from the longitudinal axis in a first direction

distal end may comprise a blunt conical tip. In other embodiments, the stylet has a distal end that is sharp.

In the present invention, the surgical instrument for passing a material into a body in a minimally invasive procedure may have the arcuate section dimensioned and curved whereby when in use and in position in the body, the arcuate section extends from the skin over the obturator foramen, through the obturator foramen, to the vaginal wall. The shape of the first member facilitates the passing of the material into the body, in a minimally invasive procedure. The shape of the first member enables a material to be placed inside the body in a minimally invasive procedure so that the material extends through the obturator foramen.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described herein with reference to the drawings wherein:

FIG. 1 is a side view of an instrument for use in a surgical procedure in accordance with an embodiment of the present invention;

FIG. 2 is a side view of an outer member of the instrument in accordance with the embodiment of FIG. 1; FIG. 3 is a bottom view of the outer member of the instrument in accordance with the embodiment of FIGS. 1 and 2;

FIG. 4 is a side view of a stylet of the instrument in accordance with the embodiment of FIGS. 1-3;

FIG. 5 is a perspective view of a length of material used with the instrument in accordance with the embodiment of FIGS. 1-4;

FIG. 6 is a sketch showing the relation of the vagina to the pelvis;

FIG. 7 is a black and white photograph of the vaginal area during an initial stage of a surgical procedure in accordance with a further embodiment of the invention;

The outer tubular member desirably has a handle at a proximal end thereof. In certain preferred embodiments, the handle has a laterally extending portion. The arcuate section defines a first plane and the wing defines a second plane substantially perpendicular to the first plane.

The surgical instrument preferably includes a material and, in certain preferred embodiments, wherein the material comprises a generally flat tape. At least one end of the tape may be cut at an angle for ease of threading the tape into the stylet, in embodiments in which the stylet comprises a slot for receipt of the at least one end. The tape desirably comprises a material including multifilament strands, which may comprise polypropylene strands. The material may comprise a generally flat tape and the stylet may have a proximal end adapted to receive an end of the tape. The material may comprise an absorbable material.

The stylet is desirably positioned in the tubular member so that the proximal end of the stylet is located adjacent a proximal end of the tubular member. In certain preferred embodiments, the stylet has a distal end that is blunt. The distal end may comprise a blunt conical tip. In other embodiments, the stylet has a distal end that is sharp.

The arcuate portion has a proximal portion which curves away from the longitudinal axis in a first direction and a distal portion which curves toward the longitudinal axis in a second direction. The shape of the first member facilitates the passing of the material into the body, in a minimally invasive procedure. The shape of the first member enables a material to be placed inside the body in a minimally invasive procedure so that the material extends through the obturator foramen.

A stylet is at least partially movable within the outer tubular member and engageable with a material to pass the material within the body. The hollow outer tubular

comprises a slot for receipt of the at least one end. The tape desirably comprises a material including multifilament strands, which may comprise polypropylene strands. The material may comprise a generally flat tape and the stylet may have a proximal end adapted to receive an end of the tape. The material may comprise an absorbable material.

The stylet is desirably positioned in the tubular member so that the proximal end of the stylet is located adjacent a proximal end of the tubular member. In certain preferred embodiments, the stylet has a distal end that is blunt. The distal end may comprise a blunt conical tip. In other embodiments, the stylet has a distal end that is sharp.

One method of suspending a portion of the urethra with a length of material comprises the steps of providing a surgical instrument having an outer tubular member including a longitudinal proximal end and a curved distal end and a stylet movable within the tubular member and configured to hold an end of the length of material. The method includes positioning the stylet within the tubular member. A vaginal incision and an incision located over the obturator foramen are made. The curved distal end of the surgical instrument is passed through the incision over the obturator foramen. The method includes manipulating the surgical instrument such that the curved distal end passes through the obturator foramen and out the vaginal incision. A proximal end of the stylet is engaged with a first end of the length of material, and the stylet is drawn through the tubular member to draw a portion of the length of material from the incision over the obturator foramen and through the vaginal incision.

The outer tubular member may be withdrawn through

the incision over the obturator foramen leaving the length of material extending through the obturator foramen and out the vaginal incision. The step of passing the curved distal end of the surgical instrument through the incision over the obturator foramen desirably includes rotating the surgical instrument approximately 30 degrees upward in relation to the body. The surgical instrument is desirably elevated to position the curved distal end through the obturator foramen. The surgical instrument is rotated to pass the curved distal end through the obturator foramen and out the vaginal incision.

Another method of suspending a portion of the urethra comprises the steps of passing a curved distal end of a surgical instrument through the body so that the instrument extends between a vaginal incision and a skin incision located over the obturator foramen. The surgical instrument has an outer tubular member including a longitudinal proximal end and a curved distal end and a stylet movable within the outer tubular member. The stylet is drawn through the body to draw the length of material through the body, extending between the vaginal incision and the incision over the obturator foramen.

The step of passing the curved distal end of the instrument desirably includes inserting the curved distal end of the instrument into the incision over the obturator foramen and moving the curved distal end through the obturator foramen, out the vaginal incision. The step of passing the curved distal end of the instrument desirably includes inserting the curved distal end into the vaginal incision. During the step of passing the curved distal end of the instrument, the stylet is desirably disposed within the outer tubular member.

The method may include, after the step of passing, withdrawing the stylet from the outer tubular member. The stylet may be reinserted in the outer tubular member so that an end of the stylet adapted to receive the material is disposed at the vaginal incision. The material is desirably disposed so that the material is received by the end of the stylet.

The step of drawing may include withdrawing the stylet through the outer tubular member, thereby drawing the material through the outer tubular member, and removing the outer tubular member through the body. The step of drawing may include withdrawing the stylet and outer tubular member from the body, thereby drawing the material through the body.

CLAIMS:

1. A surgical instrument (10) for passing a material into a body in a minimally invasive procedure comprising:

a first member (12) having a longitudinal section (16) defining a longitudinal axis and an arcuate section (18) extending distally from the longitudinal section, wherein:

a proximal portion (36) of the arcuate section curves away from the longitudinal axis in a first direction and defines a first radius of curvature (R1); and

a portion (38, 40) of the arcuate section distal of the proximal portion (36) curves toward the longitudinal axis in a second direction and defines a second radius of curvature (R2, R3).

2. The surgical instrument as recited in claim 1, wherein the first member comprises a hollow outer tubular member.

3. The surgical instrument as recited in claim 2, further comprising a stylet (14) at least partially movable within the outer tubular member and engageable with a material to pass the material within the body.

4. The surgical instrument as recited in claim 1, wherein a distal portion (40) of the arcuate section has a third radius of curvature

(R3), different from the second radius of curvature (R2).

5. The surgical instrument as recited in claim 4, wherein the portion of the arcuate section distal of the proximal portion (36) has a central section (38) and a distalmost section (40), the central section having the second radius (R2) and the distalmost section having the third radius (R3), the second radius (R2) being larger than the third radius (R3).

6. The surgical instrument as recited in claim 4, wherein the portion of the arcuate section distal of the proximal portion (36) has a central section (38) and a distalmost section (40), the central section having the second radius (R2) and the distalmost section having the third radius (R3), the second radius (R2) being smaller than the third radius (R3).

7. The surgical instrument as recited in claim 1, wherein a portion of the distal section extends across the longitudinal axis in the second direction.

8. The surgical instrument as recited in claim 3, wherein the stylet (14) is flexible.

9. The surgical instrument as recited in claim 3, wherein the stylet (14) includes a slot (28) at a first end (26) for receipt of an end of a

material.

10. The surgical instrument as recited in claim 3, wherein the stylet (14) includes a conical tip (24) at a second end.

11. The surgical instrument as recited in claim 10, wherein a diameter (d3) of the conical tip (24) is greater than an inner diameter of the outer tubular member.

12. The surgical instrument as recited in claim 2, wherein the outer tubular member (12) has a handle (20) at a proximal end (22) thereof.

13. The surgical instrument as recited in claim 12, wherein the handle has a laterally extending portion (44).

14. The surgical instrument as recited in claim 13, wherein the arcuate section (18) defines a first plane and the laterally extending portion defines a second plane substantially perpendicular to the first plane.

15. The surgical instrument as recited in claim 3, further comprising a material and wherein the material comprises a generally flat tape (50).

16. The surgical instrument as recited in claim 15, wherein at least one end (54) of the tape (50) is cut at an angle for ease of threading the tape

into the stylet.

17. The surgical instrument of claim 15, wherein the tape (50) comprises a material including multifilament strands.

18. The surgical instrument of claim 17, wherein the tape (50) comprises polypropylene strands.

19. The surgical instrument of claim 3, wherein the material comprises a generally flat tape (50) and the stylet (14) has a proximal end (26) adapted to receive an end (54) of the tape.

20. The surgical instrument of claim 18, wherein the stylet is positioned in the tubular member (12) so that the proximal end (26) of the stylet is located adjacent a proximal end (22) of the tubular member.

21. The surgical instrument of claim 3, wherein the stylet (14) has a distal end that is blunt.

22. The surgical instrument of claim 20, wherein the distal end comprises a blunt conical tip (24).

23. The surgical instrument of claim 3, wherein the stylet has a distal end that is sharp.

24. The surgical instrument of claim 1, further comprising the material and wherein the material comprises an absorbable material.